

### **REMARKS**

Claims 1-29 were at issue in this Office Action. The present response cancels claim 20. Accordingly, it is claims 1-19 and 21-29, as currently amended, which are at issue.

### **The Office Action**

In the Office Action mailed October 8, 2009, claims 1-29, all claims then pending, were rejected. Specifically, claims 1-19 were rejected under 35 U.S.C. §102 as being anticipated by the disclosure of U.S. Patent 4,990,135 of Truesdale. Claims 1, 2, 4, 6-8, 15, 17, 18, 20, 21, 23, 24 and 27-29 were rejected under 35 U.S.C. §102 as being anticipated by the disclosure of U.S. Patent 5,104,620 of Wiley. Claims 22, 25 and 26 were rejected as being obvious in view of the teaching of Wiley taken further in view of the teaching of U.S. Patent 5,076,282 of Fishman.

In addition, particular objections were made to the claims under 35 U.S.C. §112, second paragraph, and particular objections were made to the drawings.

Applicant thanks the Examiner for the Office Action and for the thorough explanation of the basis of the rejections.

### **The Objections under 35 U.S.C. §112, Second Paragraph**

Claims 1-29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite with regard to Applicant's use of the terms "proximal" and "distal". It is the Examiner's opinion that Applicant's use of these terms is in a manner contrary to their ordinary meaning, and Applicant's specification does not clearly redefine the meaning of the terms. Applicant respectfully disagrees with the Examiner in this regard. The terms "proximal" and "distal" are acknowledged in the art to be relative terms referring to the position of some point with regard to a reference point. As such, "proximal" and "distal" are analogous to referring to positions as being "near" and "far", "first" and "second", "upper" and "lower", and the like. Applicant does

note that the usage of “distal” and “proximal” throughout the specification is consistent, and these terms are used with regard to elements illustrated in the drawings and recited in corresponding portions of the specification. In this regard see the specification, for example at paragraphs [0129]-[0141]. Thus, these terms are clear and unambiguous with regard to the relative positioning of the recited elements and as such are within conventional usage. Should the Examiner disagree with Applicant’s position, Applicant is willing to either: (1) place a clarifying definition in the specification; or (2) amend the claims and specification to reverse the wording.

In a second portion of the rejections under 35 U.S.C. §112, second paragraph, the Examiner rejects claim 1 on the grounds that the limitation “said medicament or said diagnostic agent” in line 2 thereof lacks a sufficient antecedent basis. Applicant respectfully submits that this rejection is in error. Claim 1 does not include the referenced language at line 2, or at any other place therein. Clarification or withdrawal of this rejection is respectfully requested.

Claim 26 was rejected under 35 U.S.C. §112, second paragraph, on the grounds that there is no antecedent basis for the recitation of “the labeling means”. In making this rejection, and in the ongoing examination of this application, the Examiner has assumed that claim 26 is dependent on claim 25 which does recite “a labeling means”. Applicant thanks the Examiner for noting this irregularity. By the present amendment, claim 26 has been amended to depend from claim 25, rendering this rejection moot.

In addition to the foregoing, claim 1 was objected to with regard to a typographical error in line 16 wherein “slid” was written as “slided”. Applicant thanks the Examiner for noting this error. Claim 1 has been corrected accordingly by the present amendment.

**The Prior Art Based Rejections**

In a first group of prior art based rejections, claims 1-19 were rejected under 35 U.S.C. §102 as lacking novelty in view of U.S. Patent 4,990,135 of Truesdale. The Truesdale patent shows a serum inoculating device for inoculating birds. In formulating this rejection the Examiner is of the opinion that Truesdale discloses an inoculator which includes a rod house comprising a rod having a distal end and a needle having a tapering end with a recess slidably disposed, as well as a chamber house connected to the rod house. In the Office Action the Examiner further notes that various of the dependent claim features are also shown in the Truesdale patent.

Applicant thanks the Examiner for the thorough analysis and explanation. Claim 1 has been amended herewith to better differentiate over the teaching of the Truesdale patent by affirmatively reciting that the rod house is sealed by a stationary rod house sealing in the proximal end. Nowhere in Truesdale is it shown that the inoculator includes a stationary or a removable rod house sealing in the proximal end. This newly added limitation finds full support in the specification as originally filed, for example at page 6, lines 22-26. This further limitation is neither shown nor suggested in the Truesdale patent and clearly differentiates the subject matter of claims 1-19 thereover.

In a second portion of the Office Action, claims 1, 2, 4, 6-8, 15, 17, 18, 20, 21, 23, 24 and 27-29 were rejected as lacking novelty in view of U.S. Patent 5,104,620 of Wiley. The Wiley patent discloses a disposable allergy skin testing kit which is formed from a top layer sheet, a membrane sheet, and a bottom layer sheet. The bottom sheet has a plurality of capsules into which a predetermined antigen material has been deposited. The membrane sheet forms a liquid-tight seal to the capsules. The top layer sheet has an aperture in it above each of the

antigen capsules, and a pushbutton needle is mounted in each aperture. Flexible support arms are defined by portions of the top sheet, and extend from the edge of the apertures to the pushbuttons. When the pushbutton is depressed, it ruptures the antigen capsule and travels downwardly entirely through the capsule so that the needle penetrates into the patient's skin carrying the antigen material.

In contrast, the present application discloses and claims a device having a rod with a needle at its proximal end wherein the rod is **slidably** retained in the housing. The allergy skin testing system of the Wiley patent in contrast contains integral, flexible arms holding a pushbutton needle. The Wiley invention does not comprise a rod with a needle at the proximal end thereof being **slidably** retained in the housing. Consequently, the Wiley device does not include Applicant's claimed elements and does not function in the same manner as does Applicant's invention.

In making this rejection, the Examiner specifically holds that the Wiley test pad shows a rod house formed by the top layer sheet 16 wherein the pushbutton needle assemblies of Wiley 32 constitute Applicant's claimed rod which is slidably retained in the rod house (top layer sheet 16). The Examiner further holds that the bottom layer sheet 12 constitutes a first sealing and the top layer sheet 16 constitutes a second sealing. Applicant respectfully disagrees with the Examiner's characterization of the prior art as well as Applicant's claimed elements. Claim 1 recites that the rod is **slidably** arranged in the housing and that the rod is "capable of being activated by being pushed towards the proximal end of the housing". In contrast, the Wiley assembly shows a top sheet 16 having a pushbutton portion 32 attached thereto by an integral webbing of top sheet material 36 which functions as a living hinge. As will be seen from Figure

2, the pushbutton portion 32 does not in any way slide in any passage. The button 32 is merely an integral portion of the top sheet 16 which is flexed toward the second sheet 12.

The Examiner further advances the opinion, at the bottom of page 4, that the Wiley device includes the structure shown at reference numeral 50 in the figures which is connected to the rod house and constitutes a "chamber house" in accord with Applicant's claims. Applicant respectfully disagrees with the Examiner's characterization of the Wiley test pad. Reference to Figure 1 of Wiley in particular shows that the structure shown at reference numeral 50 constitutes a sheet of material which prevents the needles from penetrating the capsules prior to the intended use of the test pad. The sheet 50 is a relatively thin, planar member and in no way can be considered to constitute any type of chamber or housing. Applicant notes for the record that reference numeral 50 is not specifically mentioned in the specification of Wiley. However, the passage at column 2, lines 10-12 refers to a protective sheet which may be removably inserted into the device between the bottom surface of the top layer sheet (16) and the top surface of the membrane sheet (12). Clearly, this is the description of the sheet 50 of Figure 1. Applicant further notes that in Figure 2 the sheet 50 is shown as being partially drawn away from the device so as to permit the needle of the third unit to penetrate the bottom sheet 12. Based on a reading of the Wiley patent and a review of its drawings, it is clear that nowhere therein is shown a chamber housing in accord with Applicant's claims.

In a further portion of this particular rejection the Examiner advances the opinion that the Wiley patent shows an assembly including a first sealing constituted by the bottom layer sheet 12 and a second sealing constituted by the top layer sheet 16. Applicant notes that in the claims at issue it is further recited that a first wall of the chamber house defines a first sealing and a second wall of the chamber housing defines a second sealing. In view of this limitation, it is clear that

the structure of Wiley does not anticipate or suggest this element of Applicant's claims. In Wiley the Examiner has first of all characterized the top sheet 16 as being the rod house and subsequently has characterized it as being the first sealing. This fact defeats the rejection since the claims at issue make clear that the rod house is separate from the chamber house and the first and second sealings are constituted by first and second walls, respectively, of the chamber. If 16 is the rod house, it cannot compromise the "separate chamber house" of Applicant's claims. If it is the first sealing, in accord with Applicant's claims it must constitute a first wall of the chamber house. Thus, the top sheet 16 of the Wiley device cannot simultaneously be the rod housing as well as part of the claimed "separate chamber house". Applicant further notes that claim 1 has been amended to recite that the rod house is sealed by a stationary rod house sealing, and this element is not shown in Wiley.

In summary, Applicant respectfully submits that the Wiley patent does not show any delivery device including a rod house and a separate chamber house nor does it show any such device in which the chamber house includes a first and a second seal constituted by respective walls of the chamber house nor does it show any device in which a rod is slidably retained in a rod house. For any of the foregoing reasons, Applicant respectfully submits that Wiley does not show or suggest the presently claimed invention.

Claims 22, 25 and 26 were rejected as being obvious in view of the Wiley patent taken further in view of U.S. Patent 5,076,282 of Fishman. In view of the general inapplicability of the rejections based upon Wiley, Applicant respectfully submits that rejections based upon the combination of Wiley and Fishman are likewise overcome.

In view of the foregoing discussion and amendments, Applicant respectfully submits that all prior art based rejections are now overcome.

### The Drawings

The drawings were objected to under 37 CFR 1.83(a). It is the Examiner's opinion that the drawings do not show: (a) a device having a first sealing, a second sealing, and a removable rod house sealing as specified by claims 1 and 3; (b) a device having a rod having at least two proximal ends as per claim 20; and (c) a rod house comprising at least two rods connected at their distal ends to a common activation means as per claims 21 and 22.

In response to portion (a) of this objection, Applicant respectfully submits that Figure 8 shows a plug element with a second sealing at reference numeral 33, Figure 7 shows a plug with a first sealing at reference numeral 18, and Figure 13 shows a removable rod house sealing at reference numeral 35. These features are fully supported and shown in the drawings.

With regard to portion (b) of the Office Action, Applicant has herewith canceled claim 20 and this objection is moot.

With regard to portion (c) of this rejection, Applicant respectfully submits that the feature of claims 21 and 22 where the rod house comprises at least two rods connected at their distal ends to a common activation means is shown in Figure 11c which illustrates a multidevice in which a connector cap can activate a plurality of rods

In view of the foregoing, Applicant respectfully submits that all drawing objections are overcome.

### Conclusion

In view of the foregoing, Applicant respectfully submits that this application is now in condition for allowance. Any questions, comments, or suggestions which the Examiner may have should be addressed to the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated:

Respectfully submitted,

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